K113652

SECTION 3

510(k) Summary

OCT 3 2012

510(k) Summary

Device Name: **OrthoFix Screw**

Date Prepared: September 15, 2011

Sponsor: BONAFIX Surgical and Dental Implants, LLC
118 W Prive Cr.
Delray Beach Fl, 33445

Contact: Juan Tezak
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(561) 789-2411

Product Code: OAT

Classification Name: Class II

Classification Panel: Dental

Regulation Number: 872.3640

Common Name: Endosseous Dental Implant

Predicate Devices:

- Screw Anchor of the SYNTHES Orthodontic Bone Anchor System; SYNTHES (USA) - (reference 510(k) K093299 determined substantially equivalent on December 16, 2010).
- Dual Top Anchor System Screw; Jeil Medical Corp. - (reference 510(k) K033767, determined substantially equivalent on February 24, 2004).

Device Description: The **OrthoFix Screw** is fabricated from titanium Alloy, which meets the material requirements specified in the ASTM standard ASTM F-136-08. The head on the proximal

portion of the screw incorporates a recess, which provides an option for the orthodontist to pass through a wire and tie it in the neck of the **OrthoFix Screw** in the orthodontic treatment. Distal to the recess is a square indentation that is used as a screw head for screwing the **OrthoFix Screw** with an instrument, insertion handle tip that is connected to a commercially available insertion handle. The insertion handle tip is manufactured with a medical grade stainless steel 316L. The smooth neck distal to the proximal head employs a hole through which a wire can be passed to fix the mandible and maxilla in orthodontic treatment. Distal to the neck is the collar, which has a tapered design to protect the soft tissue. The distal portion of the proposed **OrthoFix Screw** is threaded for quick insertion and provides stability and bio mechanic retention once the screw is fully inserted. The distal tip of the screw is machined with high precision manufacturing to aid the orthodontist in self screwing or self drilling.

Intended Use:

The proposed **OrthoFix Screw** is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for a single use only. For use in adolescents greater than age 12 and adults.

Non-Clinical Test Data:

Torque testing performed on the **OrthoFix Screw** demonstrated that the torque value at fracture for the **OrthoFix Screw** is substantially equivalent to the predicate Dual Top Anchor screw of Jeil Medical Corp.

Additionally, Shear Cut and Tensile Strength (Axial) tests showed that the implant was able to withstand loads close to 80kg without presenting any kind of damage, well above the 300grs maximum load present in typical orthodontical applications.

Substantial Equivalence to Predicate Devices:

The proposed **OrthoFix Screw** is substantially equivalent to predicates devices identified above in terms of indications, principles of operation, design, geometry and materials. The table that follows provides additional details on the equivalence of the three devices

Comparison of the Proposed OrthoFix Screw to Predicate Devices			
Device Name	**Predicate Screw Anchor of the SYNTHES Orthodontic Bone Anchor System SYNTHES USA**	**Predicate Dual Top Anchor System Screw Jeil Medical**	**Proposed OrthoFix Screw BonaFix Surgical & Dental Implants, LLC**
510(k)	K093299	K033767	This Submission
Material	Medical Grade Titanium Alloy ASTM Std. unknown	Medical Grade Titanium Alloy (ASTM 136 98)	Medical Grade Titanium Alloy ASTM 136 08)
Design **Screw Head** **Neck** **Collar** **Thread**	 Hex type Through hole Regular Self Drilling and Self Tapping	 Incorporates a recess Through hole Tapered Self Drilling and Self Tapping	 Incorporates a recess Through hole Tapered Self Drilling and self Tapping
Principle of Operation	Provide fixed anchorage for orthodontic movement of teeth	Provide fixed anchorage for orthodontic movement of teeth	Provide fixed anchorage for orthodontic movement of teeth
Sizes **Diameter** **Length**	 1.55 mm 6 and 8 mm	 1.4, 1.6 & 2.0 mm 6, 8, 10 & 12 mm	 1.6 and 1.8 mm 6, 9 and 11 mm
Indications for Use	The orthodontic Bone Anchor System Screw Anchors are intended to be implanted intraorally for orthodontic procedures in adolescents greater than age 12 and adults	The device is intended to provide fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed Screws are intended for single use only. For use in adults over the age of 12	The device is intended to provide fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only For use in adolescents greater than age 12 and adults
Single use	Yes	Yes	Yes
Sterility	Provided Non sterile	Provided Non sterile	Provided sterile

Conclusion: The information provided demonstrates that the proposed device is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

Mr. Juan Tezak
President
Bonafix Surgical and Dental Implants, Limited Liability Company
118 West Prive Circle
Delray Beach, Florida 33445

Re: K113650
Trade/Device Name: OrthoFix Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: September 20, 2012
Received: September 26, 2012

Dear Mr. Tezak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2

Indications for Use

510(k) Number (if known): K113650

Device Name: OrthoFix Screw

Indications For Use:

The proposed **OrthoFix Screw** is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for a single use only. For use in adolescents greater than age 12 and adults.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113650